

falls within a limitation on the exemption contained in this subpart. For example, an investigatory record that is ordinarily exempt from disclosure under § 20.64 is disclosable to Congress in accordance with the provisions of § 20.87.

(b) Disclosure of a record to any member of the public pursuant to the provisions in § 20.81, data and information previously disclosed to the public, in § 20.82, discretionary disclosure by the Commissioner, and in § 20.83, disclosure pursuant to a court order, shall involve the rule established in § 20.21 that the record shall be made available for disclosure to all members of the public who request it. Disclosure of a record only to the limited categories of persons and under the conditions specified in § 20.84, special government employees, in § 20.85, other Federal government departments and agencies, in § 20.86, in camera disclosure in administrative or court proceedings, in § 20.87(b), Congress, in § 20.88, State and local government officials, in § 20.89, foreign government officials, and in § 20.90, contractors, which does not result in disclosure of the record to any member of the public in an authorized manner, shall not invoke the rule established in § 20.21.

(c) Disclosure to government employees and special government employees of records exempt from public disclosure shall subject those persons to the same restrictions with respect to the disclosure of such records as any Food and Drug Administration employee.

(d) In the case of a record in a Privacy Act Record System, as defined in § 21.3(c) of this chapter:

(1) The availability to an individual, as defined in § 21.3(a), of a record about himself that is retrieved by the individual's name or other personal identifier and is contained in a Privacy Act Record System shall be subject to the special requirements of part 21 of this chapter (the privacy regulations) and shall not be subject to the exemptions in subpart D of this part except that where the system is exempt and the requested record is not available under § 21.61 of this chapter, the provisions of this part shall apply.

(2) The availability of a record about an individual to persons other than the

individual who is the subject of the record shall be subject to the special requirements of part 21, subpart G, of this chapter (restrictions on disclosure in the privacy regulations), and shall not be subject to the limitations on exemptions in this subpart except as provided in part 21, subpart G, of this chapter.

§ 20.81 Data and information previously disclosed to the public.

(a) Any Food and Drug Administration record that is otherwise exempt from public disclosure pursuant to subpart D of this part is available for public disclosure to the extent that it contains data or information that have previously been disclosed in a lawful manner to any member of the public, other than an employee or consultant or pursuant to other commercial arrangements with appropriate safeguards for secrecy.

(1) For purposes of this section, an individual shall be deemed to be a consultant only if disclosure of the information was necessary in order to perform that specific consulting service and the purpose of the disclosure was solely to obtain that service. The number of consultants who have received such information shall have been limited to the number reasonably needed to perform that particular consulting service.

(2) For purposes of this section, other commercial arrangements shall include licenses, contracts, and similar legal relationships between business associates.

(3) For purposes of this section, data and information disclosed to clinical investigators or members of institutional review committees, whether required by regulations of the Food and Drug Administration, or made voluntarily, if accompanied by appropriate safeguards to assure secrecy and otherwise in accordance with this section, are not deemed to have been previously disclosed to any member of the public within the meaning of paragraph (a) of this section.

(b) Any data or information furnished to the Food and Drug Administration for a presubmission review pursuant to the procedure established in

§ 20.82

§20.44 shall be accompanied by a statement that the information has not previously been published or disclosed to anyone other than as provided in paragraph (a) of this section.

(c) Any statement relating to prior public disclosure is subject to the False Reports to the Government Act, 18 U.S.C. 1001.

[42 FR 15616, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989; 59 FR 536, Jan. 5, 1994]

§ 20.82 Discretionary disclosure by the Commissioner.

(a) Except as provided in paragraph (b) of this section, the Commissioner may, in his discretion, disclose part or all of any Food and Drug Administration record that is otherwise exempt from disclosure pursuant to subpart D of this part. The Commissioner shall exercise his discretion to disclose such records whenever he determines that such disclosure is in the public interest, will promote the objectives of the act and the agency, and is consistent with the rights of individuals to privacy, the property rights of persons in trade secrets, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.

(b) The Commissioner shall not make available for public disclosure any record that is:

(1) Exempt from public disclosure pursuant to §20.61.

(2) Exempt from public disclosure pursuant to §20.63.

(3) Prohibited from public disclosure pursuant to 21 U.S.C. 331(j), 42 U.S.C. 263g(d), 42 U.S.C. 263i, or 18 U.S.C. 1905.

(4) Contained in a Privacy Act Record System where disclosure would constitute a clearly unwarranted invasion of personal privacy or is otherwise in violation of 5 U.S.C. 552a(b), as applied in part 21, subpart G, of this chapter (restrictions on disclosure in the privacy regulations).

(c) Discretionary disclosure of a record pursuant to this section shall invoke the requirement that the record shall be disclosed to any person who requests it pursuant to §20.21, but shall not set a precedent for discretionary disclosure of any similar or related record and shall not obligate the Commissioner to exercise his discretion to

21 CFR Ch. I (4–1–00 Edition)

disclose any other record that is exempt from disclosure.

§ 20.83 Disclosure required by court order.

(a) Records of the Food and Drug Administration which the Commissioner has determined are not available for public disclosure, either in the form of a regulation published or cross-referenced in this part or by a written determination pursuant to the procedure established in §20.44, shall nevertheless be made available for public disclosure in compliance with a final court order requiring such disclosure.

(b) Where the Food and Drug Administration record ordered disclosed under paragraph (a) of this section is a record about an individual that is not available for public disclosure under §20.63, the Food and Drug Administration shall attempt to notify the individual who is the subject of the record of the disclosure, by sending a notice to the individual's last known address.

(c) Paragraph (b) of this section shall not apply where the name or other personal identifying information is deleted prior to disclosure.

§ 20.84 Disclosure to consultants, advisory committees, State and local government officials commissioned pursuant to 21 U.S.C. 372(a), and other special government employees.

Data and information otherwise exempt from public disclosure may be disclosed to Food and Drug Administration consultants, advisory committees, State and local government officials commissioned pursuant to 21 U.S.C. 372(a), and other special government employees for use only in their work with the Food and Drug Administration. Such persons are thereafter subject to the same restrictions with respect to the disclosure of such data and information as any other Food and Drug Administration employee.

§ 20.85 Disclosure to other Federal government departments and agencies.

Any Food and Drug Administration record otherwise exempt from public disclosure may be disclosed to other Federal government departments and agencies, except that trade secrets and